

PATENT COOPERATION TREATY

PCT

REC'D 23 SEP 1997

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT 0477	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/NL 96/ 00239	International filing date (day/month/year) 13/06/1996	Priority date (day/month/year) 13/06/1995
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant INTROGENE B.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of 2 sheets.

3. This report contains indications and corresponding pages relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10/01/1997	Date of completion of this report 19 SEP 1997
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  A. Huber Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Intern. application No.
PCT/NL96/00239

I. Basis of the report

1. This report has been drawn up on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

☐ the international application as originally filed.

☒ the description, pages 1-15 _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-8 _____, filed with the letter of 21.08.97,
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig 1/9 - 9/9 _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____.
☐ the claims, Nos. _____.
☐ the drawings, sheets/fig _____.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-8_____	YES
	Claims _____	NO
Inventive Step (IS)	Claims 1-8_____	YES
	Claims _____	NO
Industrial Applicability (IA)	Claims 1-8_____	YES
	Claims _____	NO

2. CITATIONS AND EXPLANATIONS

1. The present application is directed to a p53 binding protein, Mdmx, to the DNA encoding said protein and to methods for identifying proteins or nucleic acids having binding affinity for p53.

2. The quoted documents are:

D1: WO - A - 93/20238

D2: J. Sikela and W. Hahn; Proc.Natl.Acad.Sci.USA,
Vol. 84, pp. 3038-3042, 1987

D3: WO - A - 94/08241

3. The subject-matter of Claim 1 concerns a nucleic acid molecule encoding a biologically functional (part of a) p53 binding protein, which is not the Mdm2 protein and wherein said nucleic acid comprises at least a part of the sequence shown in SEQ ID No. 1.

D1 discloses the isolation of cDNA encoding mammalian Mdm2 protein. The DNA and amino acid sequences of human and mouse Mdm2 are shown in Fig. 1. Mdm2 is capable of binding to a p53 protein.

Since a p53 binding protein other than Mdm2 does not appear to have been disclosed or rendered obvious in the prior art, the subject-matter of Claims 1-6 is considered as being novel and also to involve the required inventive step (Article 33(2) PCT).

4. Claims 7 and 8 relate to a method for identifying proteins or nucleic acid molecules encoding proteins which have a binding affinity for a p53 protein. The methods comprise labelling a proteinaceous substance comprising at least the binding site of p53 and hybridizing said substance with the protein to be tested.

An analogous method for identifying binding proteins has been described in D2 for the identification of a calmodulin-binding protein. There is, however, no indication in this document that the method may also be useful for identifying proteins having binding affinity for p53.

D3 concerns a process for detecting p53-specific antibodies, which have to be regarded as p53 binding proteins. Said process, however, involves the use of labelled antibodies and not of labelled p53 protein as in present invention.

Thus, the subject-matter of Claims 7 and 8 has neither been disclosed nor rendered obvious by any of the cited documents. Said claims therefore meet the requirements of Articles 33(2) and (3) PCT.